

THE RESEARCH PROTOCOL

Protocol number: 2019/72 Revision Number: Date: 26/09/2019

1. THE NAME OF RESEARCH:	Temporomandibular Dysfunction (TMD) patients with myofascial trigger points treatment techniques in a prospective investigation of the impact on different
2. The basis and rationale of the research: <i>(up to 2500 characters)</i>	<p>Temporomandibular dysfunction (TMD); and Nov orthopedic-skeletal system changes, symptomatic pain, joint sounds, limitation of mandibular movement and fatigue of the chewing muscles characterized by(1). Emotional stress, caused by disease or TMJ occlusal disturbances, increased or dysfunctional Nov activities, it is believed that the cause of temporomandibular disorders. Nowadays, a significant increase is observed prevalencia temporomandibular joint disease(3). Usually the symptoms of TMD are complex and temporal, and occipital regions in the region that is distributed over the front preaurikuler pain is the main symptom(1).Heat, cryotherapy, local anesthesia, occlusal apparatus, physiotherapy, subcutaneous electrical neural stimulation that can reduce pain and inflammation and relaxes the chewing muscles which can reduce low-level laser (LLL) as various treatments are available for pain associated with TMD(1).The red and infrared wavelengths is used to reduce pain associated with TMD, including different pain types of clinical LLL(1).The functional relationship of the masticatory system is also commonly called splint interokluzal plaques are also temporarily healed, and is used as routine in the treatment of temporomandibular disorders(2). Temporarily removes plaque stabilization occlusal forces set up correctly and properly bring them back to the external contacts, Nov are expected to improve the symmetry of(2).</p> <p>1.Cavalcanti, M. F., et al., Comparative study of physiotherapeutic and drug the Protocol and low-level laser irradiation in the treatment of pain associated with Temporomandibular Dysfunction. Photomed Laser Surg, 2016. 34(12): p. 652-656.</p> <p>2.Alajbeg, I. Z., et al., Influence of asymmetric occlusal stabilization splints in patients with temporomandibular dysfunction of masticatory muscles activity. Coll Antropol, 2003. 27(1): p. 361-71.</p> <p>3.Slatkiewicz, T., et al., Ultrasonography diagnosis of temporomandibular disorders: a meta-analysis. Med Sci Monitor, 2018. 24: p. 812-817.</p>

<p>3. Purpose of study: (describe in detail)</p>	<p>In the literature, comparing and TMD occlusal splint in the treatment of these parameters that included the use of USG and Ill yi studies , there are no. In this study, the use of occlusal splint in the treatment of TMD and Ill as a result of USG at certain intervals and other parameters by evaluating changes in the chewing muscles, which is the treatment method is more efficient and at the same time also evaluating the parameter which is the parameters that are used in its own right is more effective because it demonstrates it is aimed to contribute to the literature.</p>
<p>4. The expected benefits of the research: (describe in detail)</p>	<p>Treatment method in the treatment of TMD, which is more efficient and can be assessed more accurately by the parameters of what they are putting forward the success of the treatment in patients with TMD.</p>
<p>5. RESEARCH METHOD: (describe in detail)</p> <p>Summarize activities you can do to perform the work: (research questions which you will answer with the work plan of the volunteer what kind of information will be collected, how the laboratory tests if you have these measurements, the methods determined to be (EXAMPLE: if you have a cell separation, which will be done how the instrument or ready-made kits to be used with, what are their technical characteristics, etc)</p>	<p>All volunteers will participate in the research that pre-treatment of joint examination and functional Ultrasonographic examination (USG) shall be governed by. The USG open and closed mouth in the application, the measurements made will be deducted from the note intervals of the left and right joints. At the same time closing the right and left masseter in closing free Nov thicknesses measured separately for all groups and will be deducted from the note and tight.</p> <p>To participate in the research volunteers will be divided into 2 groups(Laser Group: I.; Splint Group: II. Group). A randomized group of 30 people selected to be low-dose, randomized 30 will be selected again to be applied to the Laser II. the group and the group prepared by the conventional method will be applied to record the night. After treatment 1.month 3.months and 6.functional examination and the joint tests are invoked by patients for checkups month by applying the data obtained for control purposes the Note will be deducted from the USG. Laser splint after the investigation and the findings compared with each other groups, low-dose efficacy of laser therapy will be analyzed statistically.</p>

Research Design

	Observational Research		Experimental Research					
Descriptive Research	Yes between							
		Yes between						Backward Research
		Yes between						Future Research
Analytical Research	Yes between							
		Yes between						Backward Research
		Yes between						Future Research
Controlled Research			Yes between					Blind Research
			Yes X					Double-blind Research
			Yes between					Outdoor Research
				Yes between				
					Yes between			
						Yes between		
Uncontrolled Research							Yes between	
	Cross-Sectional Research	Longitudinal Research	A Randomized Controlled Trial	Non-randomised controlled trial	Cross-randomization	Before and after Research		

Other comments you may have

[Please enter information.]

6. PROCESS

Operational damage during your research, what are the issues and risks that could process?	NO
What are the precautions? (If you have a plan describe related)	NO

7. SAMPLE INFORMATION:

The number of volunteers that will participate in the research were, How explain: (used power, confidence level, average, standard deviation, and frequency (rate), etc.)	Previously a sample size of similar studies, which is located in our work are taken into consideration when calculating the reference values. Similar dental research examined; ($\mu_1 - \mu_2$) and SD is in the range 0.01 to 0.05 and values (E. V. D Chamber, 2003). When determining the sample size of the study, (at $\alpha=0.05$, $1-\beta=80\%$) and $f(\alpha, \beta)=7,85$, $sd = 0,02$ and ($\mu_1 - \mu_2$) = 0,01 is received, the sample size $n=65$ in. Our research of 60 volunteers is planned to be included.
Sampling method : (Examples, how and where will be achieved, todo how to choose the clinic?)	Patients admitted to our clinic with complaints of temporomandibular joint volunteers will be selected and randomized.

8. VOLUNTEER (SAMPLE) POPULATION INFORMATION:

Volunteers (e.g. to study) inclusion criteria : <i>(itemized List)</i>	-The applicant is over the age of 18 patients with TMJ problems -Joint and masticatory muscles of patients with pain in the region
Volunteers criteria for being included in the research : <i>(itemized List)</i>	-Syndromic patients Patients under the age of 18 -Patients with a history of orthognathic surgery -Pregnant women -Antidepressant users -Patients Who Use Removable Dentures -Patients who have had joint treatment within the last six months.
If you have a control group, which number shall be provided where functionality and how?	The control group consists of patients to be treated with splint produced by the conventional method. Patients randomized to the clinic, which will be held as a result of a joint examination by selecting this group of 30 people will be included.

Age range: <i>(please specify the number of anticipated or age limits.)</i>	
between	Children's Age Group:
	Number:
X	Over 18 years of age : 60
	Number:60
	TOTAL NUMBER:60
Gender: <i>(the gender distribution of the number planned please specify)</i>	
X	Women
X	Male
	TOTAL NUMBER:60
Informed Consent Form:	

X	Research, in a language that the participant can understand the medical words in one adjusted (as necessary medical terms given in parentheses) and is prepared in accordance with the rules? Example 1: LINK Example 2: LINK
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9. WHAT ARE THE DATA TOOLS TO BE USED IN RESEARCH? (Please attach examples of the form.)

Information-question form	
between	<input checked="" type="checkbox"/> Self-reply
between	<input checked="" type="checkbox"/> Under observation answer
between	<input checked="" type="checkbox"/> Reply through the interviewer
X	Observation
between	Lab review
between	Recording from the archives
between	Other (Please Specify.)

NOTE: a detailed list of where and in which data received from laboratory investigations on clinical and laboratory provided on-let's the word in addition to your presentation.

<p>10. WHICH statistical methods will be evaluated with the data: explain in detail the methods that will be used for statistical analysis).</p>	<p>In our study, for statistical analysis the SPSS program will be used.</p> <p>Assessments to be made of the difference between groups to be taken between categorical variables The Chi-square test will be used. The control of continuous variables normality Kolmogorov-Smirnov test will be made. Reviews the difference between the groups for continuous variables, normally distributed data student's t-test will be made. The normal distribution is not appropriate for group comparisons, Mann Whitney U test will be performed with that data.</p> <p>The average of all the continuous variables, standard deviation, minimum and maximum values given, descriptive statistics shall be specified. Frequency distributions of categorical variables and percentages shall be specified.</p>
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11. RESEARCH BUDGET: (fill in also the form of the research budget.)

Research expenses total		TRY 24834
The source of the cost of research		
	<input checked="" type="checkbox"/> The researcher himself	
	<input checked="" type="checkbox"/> Supporting	
X	<input type="checkbox"/> University (BAP)	
	<input type="checkbox"/> TUBITAK	

	<ul style="list-style-type: none"> ○ DPT
	<ul style="list-style-type: none"> ○ Industry and other institutions (please specify.)

12. THE SURVEYED CENTRES

X	Single-Center
	Very Central